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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/091,946	03/07/2002	Laurent Launay	14XZ00152	7091

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EXAMINER	
MISTRY, O NEAL RAJAN	
ART UNIT	**PAPER NUMBER**
2625	

DATE MAILED: 03/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/091,946	LAUNAY ET AL.	
	Examiner	Art Unit	
	O'Neal R Mistry	2625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 March 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,13-16,18-21 and 24-27* is/are rejected.

7)☒ Claim(s) *7-12, 17, 22, 23 & 28* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03/07/2002* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This application has been examined.

Claims 1-28 are presented for examination.

Drawings

The drawings are objected to because Figure 4 does not contain any labels to item 5 in the drawings. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The drawings are objected to because Figure 3 does not contain any labels to the x –axis and the y-axis in the drawings. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the

application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4-12 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The examiner after reviewing the specification cannot understand the meanings of

"weighting law" stated in the claim 4 line 2, claim 5 line 2, claim 6 line 2, claim 7 line 2, claim 8 line 2, and claim 9 line 2. Within the description the applicant makes no note of "weighting law", and the examiner can interpret the meaning for weighting law as gravity on the human body, or a function rule.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-6, 13-16, 18-21, 24-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Watanabe (U.S. Patent Number 6,760,611) and Azuma et al (U.S. Patent Number 6,839,457) and Harms et al (U.S. Patent Number 5,415,163).

In regards to claims 1 & 18, Azuma teaches a system for measure bone shape, structure, and architecture. In addition, Azuma discloses determine from a three-dimensional modeling a three-dimensional model known as the masked model, which features a calcified element and an implanted element, but not a vascular element (col.

2 lines 54-60) [Thus, the present invention enables the more accurate evaluation of the three-dimensional bone-related information than those by other methods, because the separated cortical bone portion three-dimensional image and the separated cancellous bone portion three-dimensional image can non-invasively and automatically be extracted at a high speed in good repeatability.]

Watanabe teaches a system to view blood vessels in the body, and produce a 3D image. In addition, Watanabe discloses determine a three-dimensional model known as the subtracted model, which features the vascular elements alone (col. 1 lines 41-48) [Utilizing this fact, NMR measurement of the region is conducted while the contrast agent remains in the blood, of the region concerned, and the obtained three-dimensional image data are processed to image the blood vessel.]

The difference between the claims and Azuma and Watanabe is the claims recite "merging the two models, weighting their voxels so as to increase the contrast between the images of the masked model and the images of the subtracted model; and summing the voxels thus weighted." In addition, Azuma and Watanabe discloses that both systems create 3-dimensional models, but does not allow a combining of the two models, even though the individual models are similar because data is extracted the same way in both systems. The examiner provides Harms for purpose to demonstrate

motivation that a combination of the two models would be obvious to one of ordinary skill in the art.

Harms teaches a system to diagnose and treating tissue suspected of containing a lesion by utilizing 3D images of bone samples, and blood samples similar to that of Azuma and Watanabe. In addition, Harms further teaches merging the two models, weighting their voxels so as to increase the contrast between the images of the masked model and the images of the subtracted model (col. 10 lines 25-30, Note that the system is combining the musculoskeletal with the vascular images to create a new image with both models.) [For example, image data from diagnostic examinations of musculoskeletal masses and bone marrow abnormalities can be used in the reconstructed slice method or combined with image processing to render three dimensional viewing, lesion specific analysis, and/or vascular images.] and summing the voxels thus weighted (col.3 lines 19-24 & col. 14 lines 31-37, Note that when the system combines the two models, the system must look a the magnetism of the voxel understand the signals, and the T1 weighting for image contrast, to add the image together) [When a group of protons precess in phase, the voxel gives off a maximum signal. When a group of protons precess out of phase, the voxel gives off no signal.] & [a useful amount of T1 weighting and improved image contrast due to the holding of magnetization in the transverse plane. It is contemplated that this embodiment of the invention would be useful for increasing

the signal from blood].

It would have been obvious to one of ordinary skill in the art, having the teachings of Azuma, Watanabe and Harms before him at the time the invention was made, to modify the system to have the ability to combine the two different models, which the first model being bone and second model being vascular, taught by Azuma and Watanabe to include the combining system that allows the two models to be merged of Harms, in order to obtain a system that has two different three-dimensional models and combine to create one three dimensional image .

One would have been motivated to make such a combination because the combination would allow a proper diagnosis of the lesion and the near tissue of the vascular and skeletal structure (col. 10 lines 40-45), as taught by Harms. In addition, Harms discloses the motivation to combine the system would provide proper treatment of the lesion tissue, because by viewing the 3-dimensional image of the combined vascular and skeletal structure would cause less damage to near by tissue while removing the lesion. Also by having the 3-deminsional image, different types of treatments may be properly applied like laser ablation treatment, ultrasonic treatment, or radiation to control the destruction of lesion (col. 10 line 43-45).

In regards to claims 2 & 19, Azuma and Watanabe and Harms discloses the masked image is filtered by removing therefrom any voxel intensities which are below a given threshold (col. 6 lines 1-5 & col. 6 lines 41-46, '457, Note the examiner interprets the claim, as the voxels are removed if the intensities are below the a certain threshold. The prior art states the luminance value which is translated to "voxel intensities", the

threshold is used to remove data that falls below the threshold, as in the Figures 3 & 4. Figure 3 is filtered and produces Figure 4, a much clear form of the image.) [In the discriminating analysis method, it is assumed that the group of luminance values is divided into two classes with a threshold in the histogram of the luminance values of images, and the threshold is determined so that the distribution ratio (f.sub.0) of the equation 1 is maximized using the interclass distribution] & [and the numerical characters of 0 were assigned to the smaller luminance values than the threshold to binarize the luminance values, whereby the binary image was obtained. FIG. 4 shows a binary image (hereinafter referred to as "binary original image") obtained by binarizing the original image of FIG. 3. From FIG. 4, it is found that the distinctions of the space portion 23 from the cortical portion 21 and the cancellous portion 22 are clear.].

In regards to claims 3 & 20, Azuma and Watanabe and Harms discloses the weighting is applied to the voxels after filtering (col. 3 lines 10-15, '611) [Each of the NMR signal groups is capable of producing a two-dimensional image or three-dimensional image. The obtained NMR signal groups may be subjected to subtraction and cumulative addition or weighted addition after each is reconstructed into image data

or may be subjected to a subtraction as measured complex signals.].

In regards to claims 4 & 21, Azuma and Watanabe and Harms discloses the voxels of the masked image are weighted by applying to them a weighting law which over at least one range of voxel intensities (col. 5 lines 30-40,'611, Note the weighted addition is used in a function to represent the image. & col. 6 lines 37-47, '457, Note the in Figure 3 is the original image, and then is converted into a Figure 4 which shows a much clearer contrast of original image, and also the luminance values are assigned to a threshold to be displayed.) [In addition, the signal processing unit 7 of the MRI apparatus of the present invention is provided with a function of performing subtraction and weighted addition for image data as a function of the CPU 8.] & [The numerical characters of 1 were assigned to the larger luminance values than the threshold, and the numerical characters of 0 were assigned to the smaller luminance values than the threshold to binarize the luminance values, whereby the binary image was obtained. FIG. 4 shows a binary image (hereinafter referred to as "binary original image") obtained by binarizing the original image of FIG. 3. From FIG. 4, it is found that the distinctions of the space portion 23 from the cortical portion 21 and the cancellous portion 22 are clear.], is a linear function of the intensity (Figure 28).

It would have been obvious to one of ordinary skill in the art, having the teachings Azuma and Watanabe and Harms before him at the time the invention was made, to modify the combining from one image to another image taught by Azuma to include the weighted addition for the image data to be displayed on the screen of Watanabe, to further include the combining of a skeletal model with a vascular model taught by Harms, in order to obtain that uses the luminance values with weighted addition image data as a function to combine two different models.

One would have been motivated to make such a combination because it would allow a much more clear image that would display fine detail in 3D of the skeletal and vascular model in determining proper diagnosis for the patient would have been obtained, as taught by Harms.

In regards to claim 5, Azuma and Watanabe and Harms discloses the voxels of the masked image are weighted by applying to them a weighting law which over at least one range of voxel intensities (col. 5 lines 30-40,'611, Note the weighted addition is used in a function to represent the image. & col. 6 lines 37-47, '457, Note the in Figure 3 is the original image, and then is converted into a Figure 4 which shows a much clearer contrast of original image, and also the luminance values are signed a threshold to be displayed.) [In addition, the signal processing unit 7 of the MRI apparatus of the present invention is provided with a function of performing subtraction and weighted addition for image data as a function of the CPU 8.] & [The numerical characters of 1 were assigned to the larger luminance values than the threshold, and

the numerical characters of 0 were assigned to the smaller luminance values than the threshold to binarize the luminance values, whereby the binary image was obtained. FIG. 4 shows a binary image (hereinafter referred to as "binary original image") obtained by binarizing the original image of FIG. 3. From FIG. 4, it is found that the distinctions of the space portion 23 from the cortical portion 21 and the cancellous portion 22 are clear.], is a linear function of the intensity (Figure 28).

It would have been obvious to one of ordinary skill in the art, having the teachings Azuma and Watanabe and Harms before him at the time the invention was made, to modify the combining from one image to another image taught by Azuma to include the weighted addition for the image data to be displayed on the screen of Watanabe, to further include the combining of a skeletal model with a vascular model taught by Harms, in order to obtain that uses the luminance values with weighted addition image data as a function to combine two different models.

One would have been motivated to make such a combination because it would allow a much more clear image that would display fine detail in 3D of the skeletal and vascular model in determining proper diagnosis for the patient would have been obtained, as taught by Harms..

In regards to claim 6, Azuma and Watanabe and Harms discloses the voxels of the masked image are weighted by applying to them a weighting law which over at least one range of voxel intensities (col. 5 lines 30-40,'611, Note the weighted addition is

used in a function to represent the image. & col. 6 lines 37-47, '457, Note the in Figure 3 is the original image, and then is converted into a Figure 4 which shows a much clearer contrast of original image, and also the luminance values are signed a threshold to be displayed.) [In addition, the signal processing unit 7 of the MRI apparatus of the present invention is provided with a function of performing subtraction and weighted addition for image data as a function of the CPU 8.] & [The numerical characters of 1 were assigned to the larger luminance values than the threshold, and the numerical characters of 0 were assigned to the smaller luminance values than the threshold to binarize the luminance values, whereby the binary image was obtained. FIG. 4 shows a binary image (hereinafter referred to as "binary original image") obtained by binarizing the original image of FIG. 3. From FIG. 4, it is found that the distinctions of the space portion 23 from the cortical portion 21 and the cancellous portion 22 are clear.], is a linear function of the intensity (Figure 28).

It would have been obvious to one of ordinary skill in the art, having the teachings Azuma and Watanabe and Harms before him at the time the invention was made, to modify the combining from one image to another image taught by Azuma to include the weighted addition for the image data to be displayed on the screen of Watanabe, to further include the combining of a skeletal model with a vascular model

taught by Harms , in order to obtain that uses the luminance values with weighted addition image data as a function to combine two different models.

One would have been motivated to make such a combination because it would allow a much more clear image that would display fine detail in 3D of the skeletal and vascular model in determining proper diagnosis for the patient would have been obtained, as taught by Harms.

In regards to claims 13 & 24, Azuma and Watanabe and Harms discloses the voxels of the subtracted model are weighted by applying to them a coefficient which is the ratio between a value that corresponds to a desired mean value for the voxels of the model in the merged model and a mean value that is calculated over the voxels in the subtracted model (col. 2 line 65- col. 3 line 3, '611, Note that weight coefficient is used for the determining the correct image of the vascular system.) [In the addition operation, each of the subtracted NMR signal groups is weighted using a weighting coefficient. The weighting coefficient is determined based on the signal intensity of the NMR signal group difference. Weighting coefficients having different signs are used.].

In regards to claims 14 & 25, Azuma and Watanabe and Harms discloses the mean value is calculated by determining the limits of the vessels or vessel portions and by calculating the mean value in the region thus determined (col. 11 lines 65- col. 12 lines 11 '611, Note the examiner interprets that the mean value is the intensity of the vessels. The prior art states steps on the re-produce a 3D image. The image takes

measurement over time and subtracts the measurements and then adds the values to create an image, in Figure 12. Figure 13 illustrates a group of vessels of a single vessel in Figure 12.).

In regards to claim 15 & 26, Azuma and Watanabe and Harms discloses the mean value is calculated by determining portions of straight lines which constitute the main directions of a vessel and by calculating the mean value over these straight lines portions (Figure 13, Note after the calculation of the data computed, the projected blood vessel image is produced, which is determining portions of straight and curved lines within the vessels. In addition to Figure 13, the system is also calculating the direction of the blood vessels, but adding the all the projections, which is time based.).

In regards to claim 16 & 27, Azuma and Watanabe and Harms discloses the anatomical region that it is desired to view is selected beforehand (col. 4 lines 29-37, '163, Note the examiner interprets that prior art must be used in a region where the patient is suspected of having a lesion, so the examiner interprets that is a form of selecting a region beforehand.) [In one embodiment, the present invention is of a method of removing a lesion from surrounding healthy tissue using a therapeutic delivery system. Multiple shaped RF pulse sequences are generated and a series of echoes are received in response thereto. A real-time MR image of tissue is produced from the series of received echoes and the produced real-time MR image is utilized to determine boundaries between the lesion and surrounding healthy tissue.], the masked model and the

subtracted model and the merged model being determined for the region (col. 10 lines 25-30, '163, Note that the system is combining the musculoskeletal with the vascular images to create a new image with both models.) [For example, image data from diagnostic examinations of musculoskeletal masses and bone marrow abnormalities can be used in the reconstructed slice method or combined with image processing to render three dimensional viewing, lesion specific analysis, and/or vascular images.].

Allowable Subject Matter

Claims 7-12, 17, 22, 23 & 28 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

In regards to claims 7 & 22, the prior art does not teach the voxels of the masked model are weighted by applying to them a weighting law which, outside of the voxel intensity range, increases less markedly than the linear function of intensity used for the intensity range.

In regards to claim 8, the prior art does not teach the voxels of the masked model are weighted by applying to them a weighting law which, outside of the voxels intensity range, increases less markedly than the linear function of intensity used for the intensity range.

In regards to claim 9, the prior art does not teach the voxels of the masked model are weighted by applying to them a weighting law which, outside of the voxel intensity range, increases less markedly than the linear function of intensity used for the intensity range.

In regards to claims 10 & 23, the prior art does not teach the weighting law used outside of the intensity range is a function which, give or take a multiplication factor, corresponds to the square root function.

In regards to claim 11, the prior art does not teach the weighting law used outside of the intensity range is a function which, give or take a multiplication factor, corresponds to the square root function.

In regards to claim 12, the prior art does not teach the weighting law used outside of the intensity range is a function which, give or take a multiplication factor, corresponds to the square root function.

In regards to claim 17 & 28, the prior art does not teach the merged model is produced by pointing to the portion or portions of vessels that the user wishes to view and automatically determining the limits of this or these portion or portions of vessels.

The prior art does not teach the modeling of the voxel outside the linear function and does not teach the use of the function of multiplication factor, corresponding to the square root. The prior art uses another method for displaying voxel on the screen.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to O'Neal R Mistry whose telephone number is (703) 305-4675. The examiner can normally be reached on 9am - 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bhavesh M Mehta can be reached on (703) 308-5246. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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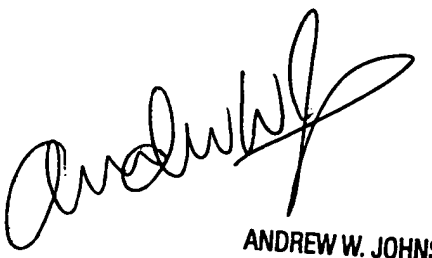

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